

Job No.: 1604-101445 Ref.: DE29905072U

Translated from German by the Ralph McElroy Translation Company 910 West Avenue, Austin, Texas 78701 USA

# FEDERAL REPUBLIC OF GERMANY GERMAN PATENT OFFICE UTILITY MODEL NO. DE 29905072U1

Int. Cl.<sup>6</sup>: A 61 M 25/06

Filing No.: 299 05 072.6

Filing Date: March 19, 1999

Publication Date: September 9, 1999

Publication in Patent Bulletin: October 14, 1999

**Priority** 

Date: March 20, 1998

Country: US

No.: G 045241

### SUBCUTANEOUS INFUSION DEVICE

Holder: Maersk Medical A/S

Lynge, DK

Agent: Tiedtke, Bühling, Kinne & Partner

80336 Munich

# **Abstract**

A subcutaneous infusion device that consists of the following:

A housing;

A flow channel in the housing;

A cannula affixed in the housing in a flow connection with the flow channel;

A self-sealing partition that covers the flow channel;

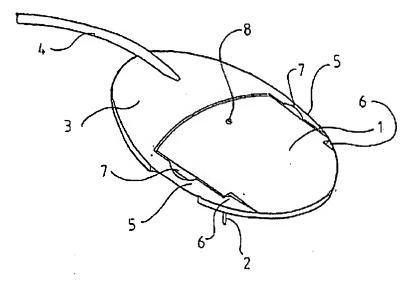
A connection device for a supply of liquid into the flow channel;

A needle on the connection device for penetration of the self-sealing partition that covers the flow channel;

An opening in the housing for insertion of an insertion needle;

A self-sealing partition for covering the opening;

Where the self-sealing partition that covers the flow channel and the self-sealing partition that covers the opening are a single element.



## Background of the design

This design concerns infusion devices for subcutaneous administration of a drug or a therapeutic fluid by means of an external infusion system and in particular it refers to an infusion device that has a device for administration of the drug or the therapeutic fluid that can be disconnected from the external infusion system.

Infusion devices are generally known in the prior art for administration of a drug or a therapeutic fluid at a subcutaneous site in a patient by means of a cannula that is introduced through the patient's skin to the subcutaneous site. Such devices usually have a tubular cannula that extends from a housing that is adapted to receive the desired drug via a separable device for suitable connection with other components of the infusion system. The possibility of separating the infusion set from the other parts of the infusion system is provided in order to improve the comfort of the user. The user can carry out activities that do not allow the presence of a pump or such or that are prevented by the presence of a pump or the like. In the separated condition only a part of the infusion set is carried by the patient. This allows increased mobility. To create such a separable device and, moreover, to maintain a fluid-tight seal to the inner part of the housing and the tubular cannula that will prevent contamination of the infusion site, such devices are usually provided with a self-sealing partition either on the housing or on the separable part and with a hollow needle on the other part, which is adapted to pass through the partition. This provides for a fluid-tight seal to the interior of the housing when the needle is pulled out of the partition. Furthermore, the partition and the needle create a fluid-tight seal between the housing and the connection device when the drug or therapeutic liquid is being supplied from the external infusion system to the patient. Subcutaneous infusion devices of this generally known kind are

known, for example, from US Patent 5522803 (Teissen-Simony) and US Patent 5545143 (Fischell).

In connection with infusion devices of this kind that have different insertion sites for the insertion needle and the needle of the connection device it is necessary for there to be a self-sealing partition at each insertion site. For this reason the manufacture of such devices is quite troublesome and time consuming.

The infusion devices up to now are, relatively speaking, space-wasting.

For these reasons there is a need for improvement to the infusion devices of the above design and in particular with respect to the provision of an infusion device that is far less complicated to make than a device that is a fluid-tight seal between the housing and the connection device in a mutual attachment position for these elements. The infusion device in accordance with the design remedies the disadvantages described above and creates additional advantages, which become apparent from the following description.

# Composition of the design

According to the design, a subcutaneous infusion device was developed, where the infusion device has the following parts:

A housing;

A flow channel in the housing;

A cannula affixed in the housing in flow connection with the flow channel;

A self-sealing partition that covers the flow channel;

A connection device for delivery of liquid into the flow channel;

A needle on the connection device for passing through the self-sealing partition that covers the flow channel;

An opening in the housing for insertion of an insertion needle;

A self-sealing partition for covering the opening;

Where the self-sealing partition that covers the flow channel and the self-sealing partition that covers the opening comprise a single element.

By providing for the self-sealing partition for covering both openings as be a single element it is possible to reduce both the material costs and the manufacturing costs without affecting the function of the infusion device. Furthermore, it made it possible to create an infusion device that is smaller than those known up to now.

In a preferred embodiment the housing has a section of the flow channel that creates a chamber, and where the opening lies opposite the chamber and where the self-sealing partition is place in the chamber.

As another advantage the self-sealing partition has a surface that is inclined both with respect to the axis of the flow channel and the axis through the opening and the cannula.

The infusion device is advantageously bonded to the patient by means of an adhesive.

The design is illustrated in more detail below with reference to the drawing.

## Brief description of the figures

Figure 1 is a perspective view of another preferred embodiment of the subcutaneous infusion device in accordance with the design;

Figure 2 is a side view of the device shown in Figure 1;

Figure 4 is a top view of the device shown in Figure 1;

Figure 3 is a cross section along line 3-3 in Figure 4;

Figure 5 is a top view of the housing of the device shown in Figure 1;

Figure 6 is a top view of the connection device of the device shown in Figure 1;

Figure 7 is a back view of the housing of the device shown in Figure 4;

Figure 8 is a front end view of the connection device of the device shown in Figure 4;

Figure 9 is a top view of a self-sealing partition;

Figure 10 is a front view of the self-sealing partition;

Figure 11 is a side view of the self-sealing partition;

Figure 12 is a side view of an insertion needle for use in connection with the device that is shown in Figure 1.

### Description of preferred embodiments

It follows from Figure 1 that the second embodiment of the infusion device has a housing 1 and a soft cannula 2 which extends from the housing. A connection device 3 is connected to the housing and tube 4 extends from the connection device in order to create a fluid connection between a pump (not shown) and the connection device 3. Two locking arms 5 are provided on the connection device 3 in order to create a locking function with respect to housing 1.

The device seen from the side can be seen in Figure 2. It immerges that an insertion device that has a needle sleeve 9 and a needle 10, was affixed in the housing and held in place by the lumen of the soft cannula 2.

It can be seen in Figure 3 that the housing 1 is provided with a drilling, where at one end of this drilling the soft cannula 2 is affixed to the drilling in a flow connection. At the end of the drilling opposite the soft cannula 2 a self-sealing partition 16 is affixed. The connection in device 3 has a drilling 13, where the hose 4 is bonded to this drilling at one end of it in a fluid connection, and where at the end of the drilling opposite the tube there is a hollow needle 12 in fluid connection with the drilling. The needle 12 is provided to penetrate the self-sealing

partition 16 in the housing. The self-sealing partition 16 provides a liquid and air seal from the surroundings, when the needle 12 of connection device 3 is pulled out of the partition and it further provides for an air and liquid seal around the needle 12 when it is inserted through the partition 16.

It can be seen in Figure 4 that the device essentially has an elliptical shape. However, the device could have any other basic shape that allows for a drilling, a self-sealing partition and a cannula in the housing and drilling, a tube and a needle in the connection device and furthermore the combined guide and locking device 5 and 6 in combination with the housing and the connection device. The two locking arms 5 on the connection device each have a barb 6 that interacts with one edge in housing 1. To separate the connection device 3 the locking arms 5 are pressed together at surface 7, which has a reduced material thickness, in order to release the barbs from the locking positions, as the connection device 3 is pulled from the housing 1.

The housing can be seen in Figure 5, according to the which the connection device has been released from the device. One can see that the housing 1 has a flat shape extending backward, which is intended to support the connection device in attached state. Recesses 18 are provided to facilitate the movement of the locking arms toward each other in an operation of separating the connection device.

The connection device 3 can be seen in Figure 6, after it was separated from housing 1. It immerges that the flexible locking arms 5 extend beyond the needle 12, through which a protective shield provided against harmful injuries that are caused by the needle. Furthermore, projecting pieces 19 are provided on each arm. These serve as a guide device for the connection device with reference to the housing and prevent unintended movement transverse to the axis of the needle.

The rear end of the housing can be seen in Figure 7. The conical entrance for the needle into element 17 is shown, and the recesses for the flexible guide and locking arms 5 and 19.

The front end of the connection device 3 can be seen in Figure 8. The needle 12 and the flexible guide and locking arms 5 are visible.

The self-sealing partition 16 is shown in Figures 9, 10 and 11 in top, front and side views. The partition 16 on its outside has the shape of a diagonally cut cylinder. It immerges that the partition, because of the diagonally cut shape has a surface that is diagonal to the flat top surface and to the backside. The inclined surface points to the interior of the housing and enables the penetration of the insertion needle in and through the soft cannula and the use of the needle of the connection device in order to supply liquid into the hollow space in the interior of the housing. However, the partition can have any shape that corresponds with the housing around the relevant openings and that permits at the same time the penetration of both the insertion needle and also the needle of the connection device, for example a partly wedge shape.

An insertion needle for use in connection with the device shown in Figure 10 can be seen in Figure 12. The insertion needle has a needle sleeve 9 and a needle 10 that, in the insertion position shown in Figure 2, extends through the soft cannula 2 via its outer tip.

The design refers to a subcutaneous infusion device that has the following: a housing; a flow channel in the housing; a cannula affixed in the housing in flow connection with the flow channel; a self-sealing partition that covers the flow channel; a connection device for supplying a liquid into the flow channel; a needle on the connection device for penetration of the self-sealing partition that covers the flow channel; an opening in the housing for insertion of an insertion needle; a self-sealing partition for covering the opening; where the self-sealing partition that covers the flow channel and the self-sealing partition that covers the opening are a single element.

By providing the self-sealing element for sealing both openings as a single sealing element it is possible to reduce both the material costs and the production costs without affecting the function of the infusion device.

### Claims

1. A subcutaneous infusion device that has the following:

A flow channel in the housing;

A cannula affixed in the housing in flow connection with the flow channel;

A self-sealing partition that covers the flow channel;

A connection device for delivery of liquid into the flow channel;

A needle on the connection device for passing through the self-sealing partition that covers the flow channel;

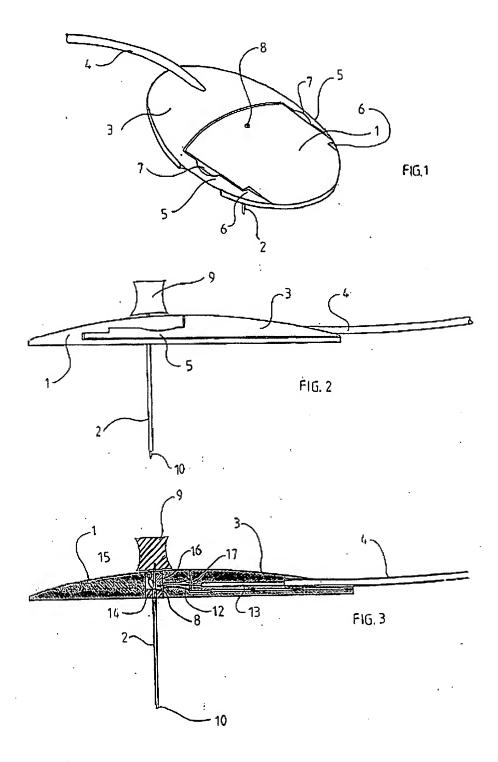
An opening in the housing for insertion of an insertion needle;

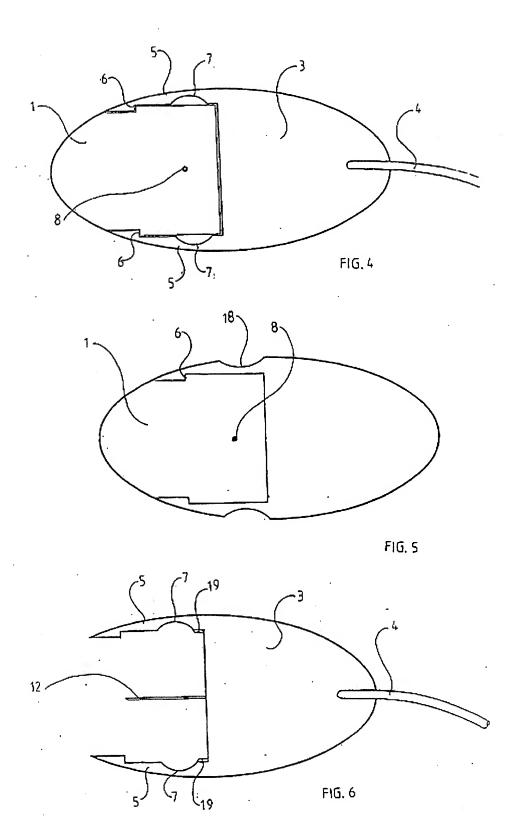
A self-sealing partition for covering the opening;

Where the self-sealing partition that covers the flow channel and the self-sealing partition that covers the opening are a single element.

- 2. A subcutaneous infusion device as in Claim 1, which is characterized by the fact that the housing includes a part of the flow channel that generates a chamber, and that the opening lies opposite the chamber and that the self-sealing partition is placed in the chamber.
- 3. A subcutaneous infusion device as in Claim 1, which is characterized by the fact that the self-sealing partition has a surface that is inclined both with respect to the axis of the flow channel and to the axis through the opening and the cannula.
- 4. A subcutaneous infusion device as in Claim 1, which is characterized by the fact that the self-sealing partition has the shape of a truncated cylinder with a diagonal angle in a relationship to the central axis.

5. A subcutaneous infusion device as in Claim 1, which is characterized by the fact that a self-sealing partition has the shape of a truncated cone, in particular a half cone.





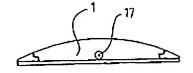


FIG. 7

